EXHIBIT 1

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ANNUAL REPORT FOR THE FISCAL YEAR 2005 ENDED DECEMBER 31,2005
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RISK FACTORS

An investment in our shares or American Depository Shares, or ADSs, involves a high degree of risk. You should consider carefully the specific risk factors described below, together with all of the other information in this annual report. The trading price of our shares and ADSs could decline as a result of any of these risks, and you may lose part or all of your investment.

Risks Related to Our Business

We are substantially dependent on the success of our lead product candidate, satraplatin. If we do not receive regulatory approval or achieve market acceptance for satraplatin, we will be unable to commercialize satraplatin successfully.

We have expended significant time, money and effort developing satraplatin. In December 2005, we completed enrollment in a Phase 3 registrational trial, the SPARC trial, testing satraplatin as a second-line chemotherapy treatment of hormone refractory prostate cancer, or HRPC. We also began the rolling submission of a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, with the goal to complete our NDA filing by the end of 2006. Before we or our partners can market and sell satraplatin, we will need to obtain necessary approvals from the FDA and similar regulatory agencies in Europe and elsewhere. Since satraplatin has received a fast track designation from the FDA as a potential second-line chemotherapy treatment for HRPC, it is eligible to be considered for an accelerated approval by the FDA. An accelerated approval could be advantageous since it may allow us to market and sell satraplatin at an earlier date than would be possible if we only seek and obtain full approval from the FDA. There is currently no procedural process in Europe equivalent to accelerated approval. As agreed with the FDA and the European Medicines Agency, or EMEA, the primary endpoint for the SPARC trial is progression-free survival and the secondary endpoints are overall survival and time to pain progression. If we seek an accelerated approval for satraplatin from the FDA, the FDA will review the progression-free survival data together with available overall survival data in considering whether to grant such an approval, whereas for any marketing authorization application filed with the EMEA, the EMEA will review such data in determining whether to grant full approval. If satraplatin is approved by the FDA on an accelerated basis it may be subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials. To obtain full approval from the FDA, we will need to submit final overall survival data to the agency for review or demonstrate that patients in the satraplatin arm of the trial derived a clear clinical benefit (such as delay in time to progression of pain) relative to the control arm.

The independent data monitoring board, or DMB, established for the SPARC trial has set a date in late April 2006 to conduct a pre-planned interim efficacy analysis of progression-free survival data from the SPARC trial. Full progression-free survival data are expected in the second half of 2006. Full overall survival data are anticipated in the second half of 2007. Although we expect data from the SPARC trial in 2006 and 2007, the timing and ultimate outcome of the review of the SPARC trial by regulatory agencies remain uncertain. With regard to the interim analysis, there also can be no assurances regarding any recommendation by the DMB based upon the interim analysis or whether data from such interim analysis would be sufficient to form the basis of a submission for regulatory approval in the United States or Europe. In addition, although satraplatin is eligible for accelerated approval by the FDA, the FDA may not grant an accelerated approval if it concludes that the progression-free survival data and available overall survival data do not demonstrate that satraplatin provides a meaningful therapeutic benefit to patients over existing treatments or that the data are otherwise inadequate to support the granting of an accelerated approval due to weaknesses, inconsistencies or differences in the data with respect to data subsets or subpopulations in the treatment group. Although the SPARC trial is modeled on an earlier 50 patient study, conducted by others, of satraplatin as a first line chemotherapy, the results from the earlier study may not accurately predict the results of the SPARC

trial. If the trial fails to demonstrate that satraplatin is safe or effective in FDA's risk/benefit evaluation, or the results of the trial are not statistically convincing, internally consistent or clinically meaningful or are otherwise deemed inadequate by the FDA, the EMEA or other regulatory agencies, full regulatory approval of satraplatin would be significantly delayed or may not be obtainable at all. Our strategy and timing for seeking regulatory approval of this drug may change depending on the results of our studies. In case of a delay, the overall costs of the program will increase and the time at which we can introduce the drug into the marketplace and begin to generate product revenues will also be delayed. Also, if regulatory approval is significantly delayed, competing therapies could be developed, which could decrease the market potential for satraplatin.

Even if we ultimately receive regulatory approval for satraplatin, satraplatin may not gain market acceptance. Furthermore, the availability of less expensive and/or more effective alternative treatments may affect our ability to successfully commercialize satraplatin.

Our other product candidates are in earlier stages of development. We may not successfully develop these product candidates. Even if their further development is successful, it will take several more years before we can file for regulatory approval of these product candidates. Therefore, if we fail to commercialize satraplatin, our ability to achieve profitability will be significantly delayed and our business prospects will be seriously limited, and you could lose all or part of your investment.

The development and commercialization of our lead product candidate, satraplatin, partially depends on the efforts of a third party and, therefore, we do not fully control its success and commercial viability in all territories around the world.

In December 2005, we entered into a co-development and license agreement for satraplatin with Pharmion GmbH, a wholly-owned subsidiary of Pharmion Corporation. Under the terms of the agreement, Pharmion has exclusive commercialization rights (including the right to develop, market and distribute) for satraplatin for Europe, the Middle East, including Turkey, Australia and New Zealand and will lead regulatory and commercial activities relating to the promotion and sale of satraplatin in those territories. We have also formed a joint development committee with Pharmion to coordinate, evaluate and expedite global development activities for satraplatin in a variety of tumor types. Pharmion has announced that, if supported by the results of the SPARC trial, they plan to file for marketing approval of satraplatin in Europe in the first quarter of 2007 but we cannot assure you that this filing or Pharmion's other development and/or commercial activities for satraplatin in its territories will be timely or ultimately successful. Our success with respect to the commercialization of satraplatin in Pharmion's territories depends largely and its development for other tumor types depends partially on Pharmion's efforts, over which we have limited control. If Pharmion is not successful or does not adequately fulfill its obligations, our business may be adversely affected.

The primary patents covering satraplatin in the United States will expire in 2008 and 2010, and in 2009 in most other countries. If we and our licensor are unable to extend the protection of these patents beyond such dates, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as satraplatin.

Even if our product candidates and technologies are covered by valid and enforceable patents, the patents will provide protection only for a limited amount of time. For example, the primary patents covering the active pharmaceutical ingredient and anticancer use of satraplatin will expire in 2008 and 2010 in the United States, respectively, and in 2009 in most other countries. Thereafter, we will have no direct means to prevent third parties from making, selling, using or importing satraplatin in the United States, Europe or Japan. Instead, we and our licensor expect to rely upon the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, and comparable foreign legislation, to seek additional product exclusivity for satraplatin. While we believe that satraplatin will meet the Hatch-Waxman criteria for patent extension, delays in the

Corporation), Metastron® (GE Healthcare/Medi-Physics, Inc.) and Taxotere® (Sanofi-Aventis S.A.). Novantrone and Quadramet are injectable pharmaceuticals approved for use in treating bone pain in cancer patients, and Emcyt is an oral drug used to relieve symptoms of advanced prostate cancer. The most recently approved of these prostate cancer drugs, Taxotere, is an injectable pharmaceutical that is approved in the United States and Europe, in combination with prednisone (a commonly used synthetic steroid), for the treatment of patients with advanced prostate cancer. Taxotere has been shown to prolong survival of patients with HRPC.

In addition to the drugs mentioned above, a Phase 2 clinical trial for Alimta® (Eli Lilly and Company) has recently been initiated, testing that drug as a second-line therapy for HRPC patients. Other examples of drugs in development for both advanced HRPC and earlier stages of prostate cancer, which may compete with satraplatin, are calcitriol (Novacea Inc.), Provenge® (Dendreon Corporation), ixabepilone (Bristol-Myers Squibb Company), Avastin™ (Genentech), Velcade® (Millenium Pharmaceuticals Inc./Johnson & Johnson Pharmaceutical Research & Development, LLC), and Nexavar® (Onyx Pharmaceuticals, Inc./Bayer Pharmaceuticals Corporation).

There are currently three marketed platinum-based drugs in the United States and in Europe. These are cisplatin, carboplatin and oxaliplatin. All three agents are administered intravenously and are not approved for the treatment of prostate cancer. In addition to these, there are other platinum-based compounds approved and/or marketed in Asian markets such as lobaplatin (China), nedaplatin (Japan) and eptaplatin (South Korea). These drugs are not approved, however, for the treatment of prostate cancer. All three of these are also administered intravenously. Another platinum-based drug, which is not currently on the market, is picoplatin. Picoplatin is administered intravenously and has shown activity for HRPC in a Phase 2 clinical trial. NeoRx has initiated a Phase 2 clinical trial with the intravenous formulation of picoplatin for the treatment of small-cell lung cancer (SCLC) that is resistant/refractory to cisplatin. If picoplatin does show efficacy in the clinic against disease that is resistant/refractory to cisplatin and if it is eventually approved for marketing, it could be a significant competitor to satraplatin. There are no reported clinical trials for an oral formulation of picoplatin. We are aware that other companies may be developing orally bioavailable platinum-based compounds. We are not aware, however, of any other orally bioavailable platinum-based compounds that are approved or are in Phase 3 clinical trials.

If 1D09C3 is approved and commercialized, it will face significant competition. Currently marketed antibodies for the treatment of non-Hodgkin's lymphoma are Rituxan® (Biogen Idec, Inc./Genentech, Inc./Roche Holdings AG), Zevalin® (Biogen Idec, Inc./Schering AG), and Bexxar® (GlaxoSmithKline). Campath® (Berlex Laboratories) is approved for chronic lymphocytic leukemia. In addition, there are a number of other antibodies and other drugs in development for the treatment of lymphoma and leukemia.

1D09C3 could also be developed for the treatment of leukemias and melanoma. There is, and will continue to be, significant competition in these markets from both large molecule drugs (antibodies and other therapeutic proteins) and small molecule drugs.

Even if our product candidates are approved for marketing, they may not be competitive with established drugs and therapies or may not be able to supplant established products and therapies in the disease settings that we target, thereby reducing the commercial value of our products.

Our operating results may fluctuate considerably on a quarterly basis. These fluctuations could have an adverse effect on the price of our shares and ADSs.

Our results of operations may fluctuate significantly in the future on a quarterly basis as a result of a number of factors, many of which are beyond our control. Although many companies may encounter this problem, it is particularly relevant to us because of our relatively small size, the fact that

we do not have any marketed products and the dynamics of the biotechnology industry in which we operate. Factors that could cause our results of operations to fluctuate include, among others:

- timing of clinical trial expenses;
- failure to achieve milestones under collaborative arrangements;
- regulatory events;
- new product introductions by us or our competitors;
- variations in the demand for products we may introduce;
- litigation involving patents, licenses or other intellectual property; and
- product failures or product liability lawsuits.

Any of the foregoing factors could cause us to fail to meet the expectations of securities analysts or investors, which could cause the trading price of our shares and ADSs to decline.

Currency fluctuations may expose us to increased costs and revenue decreases.

Our business is affected by fluctuations in foreign exchange rates between the U.S. dollar and the euro. A significant portion of our revenues are denominated in U.S. dollars but are reported in euro. Therefore currency fluctuations could cause our revenues to decline. Historically, the majority of our expenses were denominated in euro, but, on a going forward basis we expect that the majority of our expenses will be denominated in U.S. dollars. The majority of our cash and cash equivalents are denominated in euro. In addition, we conduct clinical trials in many different countries, which exposes us to cost increases if the euro declines in value compared to the currencies of those countries.

We may need substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our drug discovery, development and commercialization activities.

We may need to raise additional capital to fund our operations and clinical trials, to continue our research and development activities and to commercialize future product candidates.

We believe our cash, cash equivalents, marketable securities, and short-term investments on hand, as well as future payments we expect to receive from our collaborations with Pharmion and ALTANA Pharma and interest earned on our investments are sufficient to fund our anticipated operating requirements for at least the next 18 months. However, we may need to raise additional funds in the future. Our ability to raise additional funds will depend on financial, economic, market conditions and other factors, many of which are beyond our control. If necessary funds are not available to us on satisfactory terms, or at all, we may have to reduce expenditures for research and development and clinical trials, which could delay, reduce or eliminate our drug discovery, development and commercialization activities. Any delay in our development activities could delay our ability to commercialize a product.

Our success depends on recruiting and retaining key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy.

We depend on key members of our management team and scientific personnel. The loss of key managers or scientists, such as Marcel Rozencweig, our senior vice president for drug development, could delay the advancement of our research and development activities. We do not maintain any key man insurance. The implementation of our business strategy and our future success will also depend in large part on our continued ability to attract and retain other highly qualified

We finance our current capital expenditures out of our cash resources. Of our total capital expenditures in fiscal years 2005, 2004 and 2003, 17.2%, 29.0%, and 16.2% %, respectively, were invested in the United States.

Business Overview

GPC Biotech is a biopharmaceutical company with a mission to discover, develop and commercialize new drugs to treat cancer. We have drug candidates in different stages of development. Our drug pipeline is composed of drug candidates developed by our internal research teams as well as drug candidates that were licensed from other parties. We currently have no revenues from the sale of products.

Our lead product candidate is satraplatin, a platinum-based compound intended for use as a chemotherapy treatment. Platinum-based drugs have been clinically proven to be one of the most effective classes of anticancer therapies and are used to treat a wide range of cancers. Unlike currently marketed platinum-based drugs, satraplatin is administered orally. In December 2005, enrollment was completed in a Phase 3 registrational trial with satraplatin as a second-line chemotherapy treatment for HRPC. This study, the SPARC trial, enrolled a total of 950 patients at approximately 200 sites in sixteen countries on four continents.

There is currently no approved second-line chemotherapy treatment regimen for patients who fail first-line chemotherapy treatment for HRPC. We were therefore able to obtain fast-track designation from the FDA for satraplatin in this disease setting and we began the rolling submission of an NDA with the FDA for satraplatin in combination with prednisone as a second-line chemotherapy treatment for patients with HRPC in December 2005. To begin the rolling NDA process, we submitted to the FDA the chemistry, manufacturing and controls, or CMC, section of the NDA filing. The rolling submission process enables companies that have been granted fast track designation by the FDA to submit sections of the NDA to the agency as they become available, allowing the review process to begin before the complete dossier has been submitted. Our goal is to complete the NDA filing by the end of 2006.

Based on clinical data from earlier clinical trials, we believe that satraplatin may have application in a number of cancers. During 2005, we initiated several additional clinical trials exploring satraplatin in various tumor types and as a combination therapy with other cancer treatments.

In December 2005, we signed a major co-development and license agreement with Pharmion for satraplatin. Under this collaboration, Pharmion gained exclusive commercialization rights to satraplatin for Europe, the Middle East, including Turkey, Australia and New Zealand. We retain our current rights to the U.S., as well as other key non-European markets, including Japan.

Our second most advanced product candidate is 1D09C3, a monoclonal antibody that is in a Phase 1 clinical trial and is intended for the treatment of selected leukemias and lymphomas, including non-Hodgkin's lymphoma. A monoclonal antibody is an immune system related protein that binds preferentially to one type of foreign substance, potentially stimulating a biological response. We initiated a clinical trial for 1D09C3 early in 2005. The aim of this trial is to assess the safety of this drug and to recommend a dose for Phase 2 clinical trials. Furthermore, we have several distinct research programs to discover new anticancer drug candidates.

In addition to our research and development programs, we also have an ongoing technology collaboration with ALTANA Pharma pursuant to which we are assisting ALTANA Pharma with its research institute in the United States. This agreement includes a research collaboration as well as a transfer of technologies. Effective January 2003, we also entered into another collaboration agreement with ALTANA Pharma pursuant to which we licensed LeadCode™.

purposes of this meeting included assessing the safety of the drug in earlier trials, evaluating our Phase 3 registrational trial plan, and identifying any additional information that would be needed to support an NDA. Additionally, we requested a review of our Phase 3 registrational trial protocol under the FDA's Special Protocol Assessment program. The combination of the "End-of-Phase 2 Meeting" and the Special Protocol Assessment provided us the opportunity to hold meaningful discussions with the FDA regarding our overall registrational approach. As a result, the FDA confirmed its agreement with us that successful completion of the SPARC trial will form the primary basis for an efficacy claim for our NDA for satraplatin, if executed flawlessly. This agreement becomes part of the administrative record and may only be changed by mutual agreement of the parties or if the FDA identifies a substantial scientific issue relevant to safety or efficacy after the trial has begun. The FDA has also granted fast track designation to satraplatin as a second-line chemotherapy treatment for patients with HRPC. The FDA's fast track program is intended to facilitate the development and expedite the review of drugs that treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The fast track designation enables us to file sections of the NDA on a rolling submission basis, submitting sections as they become available. In December 2005, we began the rolling NDA submission for satraplatin, submitting the CMC section.

We have also received a Scientific Advice Letter in 2004 and Additional Scientific Advice from the EMEA in 2006 relating to our Phase 3 clinical trial. Although the Scientific Advice Letter was not required for the initiation of a Phase 3 clinical trial in Europe, it was helpful because it allowed the EMEA to comment on our overall registrational approach before implementation. Pharmion now has primary responsibility for regulatory activities and filings for Europe and disclosed that in its 2006 Additional Scientific Advice, the EMEA confirmed that it would accept the final analysis for progression-free survival from the SPARC trial and the available overall survival data as the basis for an efficacy claim in the submission of a marketing authorization application.

In September 2003, we initiated the SPARC trial. The SPARC trial is a multinational, multicenter, randomized, double-blind Phase 3 registrational trial to test satraplatin plus prednisone versus a placebo plus prednisone in patients with HRPC whose disease has progressed on first-line chemotherapy. "Randomized" means that patients are randomly assigned to receive the drug candidate or a placebo. To encourage participation, we have set the randomization ratio at 2:1 in favor of active treatment. "Double-blind" means that neither the physician nor the patient knows whether the patient has received the drug candidate or a placebo. "Progressed on first-line chemotherapy" means that a patient with HRPC has shown further advancement of their cancer while being treated with a regimen that includes a chemotherapy drug. The SPARC trial is designed to determine the efficacy and evaluate the safety of satraplatin plus prednisone in slowing the progression of cancer in this patient population. According to the criteria we have discussed with the FDA and the EMEA, the trial was designed to detect a 30% or greater increase in the period of time required for the progression of disease to occur in the treatment group, as compared with the control group. In December 2005, enrollment completed in the trial, with a total of 950 patients enrolled at approximately 200 clinical centers in sixteen countries on four continents.

During the course of the SPARC trial an independent data monitoring board, or DMB, established in accordance with guidelines provided by the FDA, meets periodically to review the results of the trial and evaluate the safety and/or efficacy of satraplatin in the trial population. The DMB makes recommendations to us regarding the continuation, modification or discontinuation of the trial based on its review of safety and efficacy data. To date, the DMB has held three meetings—one in 2004 and two in 2005—each focused on a review of safety data from the trial. After each of these meetings, the DMB reported that the design and conduct of the trial remained sound and recommended that the trial continue as planned. The third of these safety reviews was held in December 2005, based on 592 patients. The DMB has also set a date in late April 2006 to conduct a pre-planned interim efficacy analysis of data from the SPARC trial. There can be no assurances regarding any recommendation by

threatening condition for which there is no effective treatment and that demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine whether the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in the PDUFA, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- ***Priority Review.*** Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA's criteria for priority review. We cannot guarantee any of our drug candidates will receive a priority review designation or, if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately grant drug approval.

- ***Accelerated Approval.*** Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Although we have obtained a fast track designation from the FDA for our development of satraplatin to treat HRPC patients who have failed prior treatment with chemotherapy, we cannot guarantee a faster development process, review process or approval compared to conventional FDA procedures. Based upon an agreement reached with the FDA in 2005, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival. Although satraplatin is eligible for accelerated approval by the FDA, the FDA may not grant an accelerated approval if it concludes that the progression-free survival data and available overall survival data do not demonstrate that satraplatin provides a meaningful therapeutic benefit to patients over existing treatments or that the data are otherwise inadequate to support the granting of an accelerated approval due to weaknesses, inconsistencies or differences in the data with respect to data subsets or subpopulations in the treatment group. Our strategy and timing for seeking regulatory approval of this drug may change depending on the results of our studies.

review phase of testing required under the Federal Food, Drug, and Cosmetic Act. The IND testing phase is measured as the time between the effective date of an IND and the date the FDA receives the NDA; the NDA review phase is the time between the FDA receives the NDA and approval of the NDA. However, any testing conducted prior to patent issuance is not considered for patent extension. The maximum total patent term remaining after term extension is capped at fourteen years. Similarly, absolute caps limit the duration of term extension to five years. Furthermore, a patent is only eligible for one term extension. This patent term extension is only available for the first commercial marketing of a given active ingredient. In addition, the product must have been subject to regulatory review before its commercial marketing or use, and the resulting permission for commercial marketing or use must be the first granted. As a practical consequence generally, only one patent may be extended per approved product. Also, the original patent must still be in force when the application for term extension is filed, and the application must be filed by the patent owner of record or its agent. The application for patent term extension is subject to approval by the USPTO. The FDA, however, determines the length of the product's regulatory review period at the request of the USPTO. In some instances, the term of the patent for which a patent term extension is being requested may expire before such an extension is granted.

The Hatch-Waxman Act also provides for data exclusivity for the data demonstrating safety and efficacy of a drug product as submitted in an NDA: five-year new chemical entity, or NCE, exclusivity and three-year new clinical trial exclusivity. Five-year NCE data exclusivity is granted to those drugs for which the active ingredient is an active moiety (*i.e.*, the molecule or ion responsible for physiological or pharmacological action, excluding appended portions that would cause the drug to be an ester, salt, or other noncovalent derivative of the molecule) not previously approved by the FDA. Five-year NCE data exclusivity prohibits the FDA from accepting an ANDA or Section 505(b)(2) application for a drug product containing the same active moiety for a five-year period beginning from the date of approval of the NDA. The only exception to this prohibition on the FDA's acceptance of an ANDA or Section 505(b)(2) application is if a generic competitor challenges patents listed in the Orange Book for the drug product at the end of four years. The five-year exclusivity provision, however, does not prohibit the FDA from accepting another full NDA, for example from a competitor, if the sponsor of the second application has done all the work itself. The FDA can accept the second application, review it, and approve it; NCE exclusivity only prohibits the agency from accepting a Section 505(b)(2) application or an ANDA.

The Hatch-Waxman Act requires an applicant for an ANDA to submit a certification for each patent listed in the Orange Book. This certification requirement also extends to Section 505(b)(2) applications. One of four certifications must be made: 1) that the drug has not been patented; 2) that the patent has already expired; 3) the date on which the patent will expire, and that the generic drug will not go on the market until that date passes; and 4) that the patent is not infringed or is invalid. Those certifications are now referred to as paragraph I, II, III, or IV certifications. Whereas the first three certifications are relatively straightforward, the paragraph IV certification presents added requirements.

When an ANDA contains a paragraph IV certification, the applicant is required to notify the innovator company that it has filed the ANDA with the FDA, and describe the reasons it believes the patent will not be infringed, is invalid, or is unenforceable. The only exception to this rule is if a company is not seeking approval for one of the drug's uses. In that case, an applicant may submit a "Section 8" statement that the company is not seeking approval for a particular use. Once the innovator company receives notice that a generic application has been filed and its patent is being challenged, the innovator drug company has 45 days in which to file a lawsuit claiming patent infringement based on the generic drug company's assertion about the characteristics of its proposed product. The filing of a lawsuit as a result of the paragraph IV notice has a substantial effect on the time of approval of the ANDA or 505(b)(2) application. If a lawsuit is brought by the innovator drug company, the FDA's final